

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK**

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	)	<b>Case No. 18-cv-06650</b>
	)	<b>Hon. Carol Bagley Amon</b>
<b>JOSE MELENDEZ, JANE DOE,</b>	)	
<i>individually and on behalf of</i>	)	
<i>all others similarly situated,</i>	)	
	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
<b>ONE BRANDS, LLC,</b>	)	
	)	
Defendant.	)	

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**REPLY IN SUPPORT OF DEFENDANT’S MOTION TO DISMISS**  
**PLAINTIFF’S PUTATIVE CLASS ACTION COMPLAINT**

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## INTRODUCTION

ONE Brands demonstrated in its motion to dismiss that only Plaintiff's New York damages claims are properly before the Court and that each of those claims fail because they are (1) preempted by federal law and (2) inadequately pleaded. *See* Memorandum in Support of Motion to Dismiss ("Mot.") at 9-33 (June 21, 2019). Plaintiff's opposition concedes that his allegations, involving other states' laws, are irrelevant at this stage in the case. *See* Response to Motion to Dismiss ("Resp.") at 12 (July 12, 2019). Plaintiff also makes no argument that he has plausibly pled each element of his remaining New York causes of action. Based on this pleading deficiency alone, the entire amended complaint can—and should—be dismissed.

Plaintiff *only* argues that his New York General Business Law Sections 349 and 350 claims are not preempted. But even those arguments, that need not even be considered, fail. First, contrary to Plaintiff's assertion, federal law permits challenges to nutrient content claims, *e.g.*, that a product contains one gram of sugar, only if a plaintiff pleads that the FDA-required testing showed that the nutrient content claim is false. Plaintiff's amended complaint contains no such allegation, and Plaintiff's efforts to skirt this requirement are meritless. Second, federal law authorizes companies to make factual statements about the amount of a nutrient on the product's packaging. *See* 21 C.F.R. § 101.13(i). Rather than addressing the actual statements on the label, Plaintiff imagines and then addresses a statement that

appears nowhere on the label. Finally, federal law does not require bare statements regarding the amount of sugar to be accompanied by statements regarding the amount of other nutrients. Plaintiff nonetheless would impose such a requirement, which is contrary to federal law. As a result, Plaintiff's claims are preempted and should be dismissed, in addition to the other un rebutted reasons set forth in ONE Brands' motion to dismiss.

## **ARGUMENT**

### **I. Plaintiff has failed to state a claim.**

ONE Brands demonstrated that each of Plaintiff's six New York counts are inadequately pleaded. *See* Mot. § III.A (explaining that Plaintiff failed to state a claim under N.Y. Gen. Bus. Law §§ 349 and 350); *id.* § III.B (same for breach of warranty); *id.* § III.C (same for fraud); *id.* § III.D (same for negligent misrepresentation); *id.* § III.E (same for unjust enrichment). Plaintiff has offered no response to any of these arguments in his opposition. As a result, Plaintiff has abandoned these claims. *See, e.g., Thomas v. N.Y.C. Dep't of Educ.*, 938 F. Supp. 2d 334, 354 (E.D.N.Y. 2013) (citing *Williams v. Mirabal*, 2013 WL 174187, at \*2 (S.D.N.Y. Jan. 16, 2013); *Lipton v. Cty. of Orange, N.Y.*, 315 F. Supp. 2d 434, 446 (S.D.N.Y. 2004)). For this reason and those provided in ONE Brands' motion, the complaint should be dismissed in the entirety. If the Court determines that Plaintiff

has abandoned these claims or that they are inadequately pleaded, it need not reach the subsequent arguments.

## **II. Plaintiff's claims are preempted.**

Plaintiff only argues that his N.Y. Gen. Bus. Law §§ 349 and 350 claims are not preempted. Plaintiff acknowledges, however, that “[f]ederal law explicitly bars state and local governments from adopting food labeling requirements that are ‘not identical to’ the federal requirements established by the Nutrition Labeling and Education Act.” Resp. at 4. Plaintiff also acknowledges that his state-law claims must fit within a “narrow gap” to escape express and implied preemption. *Id.* Plaintiff argues that ONE Brands’ “one gram of sugar” statements are not preempted for three reasons: (1) they are false based on Plaintiff’s undisclosed testing; (2) they are per se misleading because FDA has not authorized such statements; and (3) they are misleading because consumers would incorrectly believe that the ONE Bars are also low in calories and carbohydrates. Each of these claims is preempted and comes nowhere close to fitting in the “narrow gap” necessary to avoid preemption.

A. Plaintiff’s claim that ONE Brands’ “one gram” statement is false is preempted by federal law because Plaintiff has not conducted the FDA-required testing. *See* Mot. at 16-18. As ONE Brands explained in the motion to dismiss, federal law dictates that compliance with federal law “be determined” in a particular way (because some variability is expected and unavoidable). *See id.* at 17.

Specifically, federal law requires “[t]he sample for nutrient analysis [to] consist of a composite of 12 subsamples” and “be analyzed by appropriate methods as given in the ‘Official Methods of Analysis of the AOAC International.’” 21 C.F.R. § 101.9(g)(2). Plaintiff’s complaint makes clear that he did not follow these requirements. He tested only one sample, not twelve. Plaintiff has also neither alleged that he followed the AOAC requirements nor agreed to provide ONE Brands with his testing so a determination can be made whether AOAC methods have been followed. Numerous federal courts have concluded that similar failures render plaintiffs’ claims preempted because, without such allegations, it is impossible to show that a plaintiff is not imposing additional or different requirements from those imposed by FDA. *See* Mot. at 17 (collecting cases); *see also Welk v. Nutraceutical Corp.*, 2018 WL 3818033, at \*4-5 (S.D. Cal. Aug. 10, 2018) (collecting other cases and dismissing claims); *Dougherty v. Source Nats., Inc.*, 148 F. Supp. 3d 831, 836-37 (E.D. Mo. 2015) (same). This Court should too.

In response, Plaintiff makes two arguments, neither valid. First, Plaintiff claims that the federal regulation is “inapplicable” because Plaintiff (and other consumers) do not “have access to 12 different randomly chosen shipping cases.” Resp. at 9. But no such exception exists under federal law, and as noted above and in the motion, numerous federal courts have determined that plaintiffs must show that they complied with the testing requirements. And of course Plaintiff could have



randomly selected bars from 12 different lots to test. Plaintiff instead relies on FDA Guidance for Industry from 2008 that did not require *manufacturers* to test a specific number of samples. All that guidance says is that a manufacturer may need to test more or less than the 12 samples to ensure it stays in compliance with the law. But the guidance and the law are clear that to bring “enforcement actions” for violations of the labeling requirement, the case *must* be based on “a composite of 12 units.” Resp. at 10.

Second, Plaintiff states that he “does not invoke the results of [his] independent, [AOAC-based] testing to show that the amount of sugars ‘is greater than 20 percent in excess of the value for that nutrient,’” Resp. at 11, but his testing “is intended to allow the Court to ‘infer that tests conducted in compliance with the 12-sample methodology would support Plaintiff’s allegations that the Product is mislabeled,’” *id.* (quoting *Smith v. Allmax Nutrition, Inc.*, 2015 WL 9434768, at \*7 (E.D. Cal. Dec. 24, 2015)). Put another way, Plaintiff believes the federal requirements are relevant only “if it was a ‘close call’” whether a nutrient content claim was correct at the pleading stage. *Id.* But this argument makes no sense.

For one thing, the federal regulations have no “close call” exception. For another, preemption is a question of law that is routinely decided at the pleadings stage, particularly where federal law expressly precludes certain claims. *See, e.g., Marentette v. Abbott Labs., Inc.*, 201 F. Supp. 3d 374, 385 (E.D.N.Y. 2016) (Organic

Foods Production Act of 1990), *aff'd*, 886 F.3d 112 (2d Cir. 2018); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 279-82 (E.D.N.Y. 2009) (Medical Device Amendments). Here, there is no contention that Plaintiff actually conducted the required testing, nor has Plaintiff provided a copy of his testing to support his allegations. His testing-based claim is preempted.

Plaintiff's cited cases do not require a different result. *Erickson v. Pardus*, 551 U.S. 89, 93 (2007), and *LeChase Construction Services, LLC v. Escobar Construction, Inc.*, 2019 WL 2743637 (N.D.N.Y. July 1, 2019), involve neither labeling claims nor preemption. *Smith v. Allmax* and the two Northern District of Illinois cases address the relevant issue, *see* Resp. at 11, but they are contrary to the vast majority of cases, *see, e.g.*, Mot. at 17. Moreover, they are contrary to *Twombly* and *Iqbal*, which require plaintiffs to state plausible claims, and in this area—as Plaintiff is well aware—a plausible claim is one that is not plainly preempted. *See Horowitz*, 613 F. Supp. 2d at 283 n.5 (“requiring amplification as to how the defendants’ alleged federal violations relate to the plaintiff’s claims is exactly what *Twombly* contemplates, especially where such a connection is implausible”).

Further, Plaintiff’s attempt to distinguish the cases cited by ONE Brands that adopt the majority position is not well taken. *See* Resp. at 10. Preemption applies equally to mandatory statements in the Nutrition Facts and to nutrient content claims on the front of the packaging. *See* 21 U.S.C. § 343-1(a)(5); *see also* 21 U.S.C. §

343(r)(1) (regulating “claims”); 21 C.F.R. § 101.13(b) (regulating “claims” “on the label or in labeling”). And the mandatory testing requirement applies to all nutrient content claims. *See* 21 U.S.C. § 343(r) (governing claims “made in the label or labeling of ... food which expressly or by implication ... characterizes the level of any nutrient”); 21 C.F.R. § 101.13(o) (noting that compliance determined by § 101.9(g)(2) methodology). Indeed, *Mee* and *Baker* did concern claims made outside the Nutrition Facts, and given the nature of Plaintiff’s claim, there is no basis on which to distinguish the other cases. *See* Mot. at 17. As a result, the testing-based claim should be dismissed.

B. Plaintiff’s claim that ONE Brands’ one-gram statement is misleading because it does not comply with 21 C.F.R. § 101.60 is also preempted. To start, efforts to directly enforce the Food, Drug and Cosmetics Act are impliedly preempted as there is no private right of action. *See Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). But more importantly, federal law expressly authorizes ONE Brands to make truthful statements regarding the amounts of nutrients in ONE Bars. *See* Mot. at 18-19 (citing 21 C.F.R. § 101.13(i); 58 Fed. Reg. 2302, 2310 (Jan. 6, 1993)). This claim is accordingly preempted.

In response, Plaintiff makes two incorrect arguments. First, Plaintiff contends that 21 C.F.R. § 101.60 controls his claim, not § 101.13, and because § 101.60 does not expressly authorize statements regarding the amount of sugar in a product, they

are not permitted. Resp. at 5. However, the FDA has expressly said that “simple statement[s] of amount . . . can appropriately be included in food labeling.” 58 Fed. Reg. 2302, 2310 (Jan. 6, 1993). In the preamble to the final nutrition labeling regulations, FDA stated:

FDA finds that there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food. For example, the statement “100 calories” or “5 grams of fat” on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient. As long as such a statement is not false or misleading, it can appropriately be included in food labeling. Therefore, FDA is providing in new § 101.13(i)(3) that an absolute statement of amount may be made without a disclaimer if “[t]he statement does not in any way implicitly characterize the level of the nutrient in the food, and it is not false, or misleading in any respect.”

58 Fed. Reg. 2302, 2310 (Jan. 6, 1993); *see also* 59 Fed. Reg. 378, 385 (Jan. 4, 1994) (reiterating the agency’s position regarding statements of amount).<sup>1</sup>

Moreover, as ONE Brands explained in the motion, Plaintiff’s proposed interpretation of the regulations puts them in direct conflict. Mot. at 19 & n.7. Section 101.13(i) permits statements regarding “the amount or percentage of a nutrient if . . . [t]he statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading.” The regulation provides

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<sup>1</sup> *See also* FDA, Guidance for Industry and FDA, Dear Manufacturer Letter Regarding Food Labeling (Jan. 2007) (emphasis in original), *available at* <http://bit.ly/2GVgsOF> (“An accurate quantitative statement (e.g., 200 mg of sodium) may be used to describe any amount of a nutrient present.”).

“100 calories” as an example of a permissible statement. *Id.* This example is key to understanding the relationship between sections 101.13 and 101.60 because if the only claims regarding calories or sugar that are authorized were those covered by § 101.60, then a statement that a product contained 100 calories would not be allowed. *See* 21 C.F.R. § 101.60(b). Reading statutes and regulations to nullify one another is contrary to established principles of legal interpretation. *See W. Va. Univ. Hosps., Inc. v. Casey*, 499 U.S. 83, 101 (1991). Instead, the regulations should be read in harmony, which would mean that statements regarding the amount of a nutrient, including sugar, in a product are permitted.

Plaintiff does not necessarily dispute ONE Brands’ reading of the two sections. He instead tries to distinguish a statement that ONE Bars contains one gram of sugar from a statement that a product contains 100 calories. Resp. at 5. However, there is no meaningful distinction between the two statements, nor does Plaintiff offer a convincing one. Additionally, Plaintiff objects to the fact that ONE Brands’ “‘1 g of sugar’ is touted in comparison to its 20g of protein” statement, Resp. at 6, but there is no support for that claim and it is contradicted by the label itself. *See* Am. Compl. ¶ 5, 21. *See also In re Edgewell Personal Care Co. Litig.*, 2018 WL 7858623, at \*5 (E.D.N.Y. Sept. 4, 2018) (recognizing that the Court is “well-equipped” to answer whether a reasonable consumer would find a claim to be misleading).

Second, rather than addressing the statements that are actually in the ONE Bar packaging, Plaintiff tries to convert “one gram of sugar” into “low sugar,” even though the ONE Bar labeling does not contain such a statement. However, because the labeling does not contain a “low sugar” statement and Plaintiff does not allege that ONE Brands used those words, this argument should be rejected.

C. Finally, Plaintiff claims that “ONE Bar” and “One Gram of Sugar” are misleading implied nutrient content claims because they supposedly could be understood to mean that ONE Bars are low in other nutrients (calories and carbohydrates). *See* Resp. 6-7. However, this argument is also contrary to federal law and common sense. A “direct statement about the level (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘contains 100 calories.’” is an “expressed nutrient content claim” because it is a statement of amount. 21 C.F.R. § 101.13(b)(1). ONE Bar and the one-gram statement are thus expressed nutrient content claims as defined by federal law, not implied claims. Because Plaintiff’s argument turns on his incorrect characterization of the statements as implied nutrient content claims, it fails.

Plaintiff’s citation to 21 C.F.R. § 101.69 and Carbolite do not help him either. Section 101.69 only governs *petitions* for new not yet permitted nutrient content claims and “implied claim[s] in a brand name,” *id.* § 101.69(b). This is inapplicable because the “one gram” statement is a permitted expressed claim (statement of

amount), where no petition was required (and ONE Brands filed no petition). Nor is the ONE Bar name an implied nutrient content claim—it contains no nutrient and it has no comparative term regarding the level of a nutrient. Compare this to “Carbolite” that includes a “carb” a short hand for carbohydrate (a nutrient) and “lite” (which characterizes the level of the nutrient and is listed in the definition of an implied nutrient content claim). Because ONE Brands’ statement is not an implied claim, this section is inapplicable, and the analogy to the Carbolite petition is irrelevant. *See* Resp. at 7.

As explained in the motion to dismiss, Plaintiff’s claims are preempted. His arguments to the contrary are meritless. Thus, the amended complaint should be dismissed.

### **III. Plaintiff lacks standing to pursue injunctive relief.**

Plaintiff acknowledges that his attempt to bring a class action on behalf of all consumers nationwide is not before the Court—only his personal New York law claims are at issue currently. *See* Resp. at 12. However, Plaintiff seeks both damages and injunctive relief under his own claims, but as ONE Brands showed, *see* Mot. at 11-13, Plaintiff lacks standing to seek injunctive relief going forward. Plaintiff cites two cases in response, which permitted plaintiffs to proceed with claims for injunctive relief even though they did not intend to purchase the product again. *See* Resp. at 12. But those cases misapply Supreme Court and Second Circuit

precedent. This Court has recognized that “[p]ast injuries ‘do not confer standing to seek injunctive relief unless the plaintiff can demonstrate that she is likely to be harmed again in the future in a similar way.’” *In re Edgewell*, 2018 WL 7858623, at \*14 (quoting *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016)). That is all Plaintiff has here: an allegation of past injury with no intention of purchasing ONE Bars again. As a result he lacks standing to seek injunctive relief.

### CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiff’s complaint with prejudice. Plaintiff has already amended his complaint once in response to ONE Brands’ motion to dismiss letter. Plaintiff should not be given a third chance.

Dated: August 2, 2019

Respectfully submitted,

/s/ Benjamin M. Mundel

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## **CERTIFICATE OF SERVICE**

I hereby certify that on August 2, 2019, I caused a copy of the foregoing Memorandum of Law in Support of Defendant's Motion to Dismiss Plaintiff's Putative Class Action Complaint to be served on the following counsel via email:

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